

Hitachi Aloka Medical, Ltd.

**510(k) Summary of Safety and Effectiveness in accordance with  
21 CFR Part 807, Subpart E, Section 807.92.**

21 CFR 807.92, Subsection a

**1. Submitter's Information**

Hitachi Aloka Medical, Ltd.  
10 Fairfield Boulevard  
Wallingford, CT 06492-5903

Contact:  
Angela Van Arsdale  
RA/QA Manager

Telephone: (203) 269-5088 Ext: 346  
Fax Number: (203) 269-6075

Date Prepared: December 18, 2013

**2. Device / Common / Classification Name / Classification / Product Code:**

Device Proprietary Name – Arietta70 / AriettaS70/ AriettaV70 Diagnostic Ultrasound System  
Common name - Diagnostic Ultrasound System and Transducers  
Classification name - System, Imaging, Pulsed Doppler, Ultrasonic  
Classification: Class II  
Product Code: 90-IYN 892.1550 Ultrasonic Pulsed Imaging System  
90-IYO 892.1560 Ultrasonic Pulsed Echo Imaging System  
90-ITX 892.1570 Diagnostic Ultrasound Transducer

**3. Legally Marketed Predicate Device(s):**

Hitachi HI VISION Ascendus Diagnostic Ultrasound Scanner [K110673]  
Hitachi Prosound F75 Diagnostic Ultrasound Scanner [K123828]

**4. Device Description:**

An ultrasound diagnostic system with the following features:

- Ultrasound transducer(s) – to generate the transmitted ultrasound energy and detect the reflected echoes
- Ultrasound transducer accessories (standard and optional) - to maximize functional usage of transducer(s) in various modes of operation
- A computer system - to control the transducer and analyze the signals resulting from the reflected echoes
- A video monitor with optional image recorder - to display the computed image or derived Doppler data

**5. Indication for Use:**

The Hitachi Aloka Medical, Ltd. Arietta70/ AriettaS70 /AriettaV70 is intended for use by trained personnel (doctor, sonographer, etc.) for the diagnostic ultrasound evaluation of Abdominal, Cardiac, Intra-operative, Fetal, Pediatric, Small Organ, Peripheral vessel, Biopsy, Trans-rectal, Trans-vaginal, Musculoskeletal, Neonatal Cephalic, Adult Cephalic, Endoscopy, Intra-luminal, Gynecology, Urology and Laparoscopic clinical applications.

The Modes of Operation are B mode, M mode, PW mode (Pulsed Wave Doppler), CW mode (Continuous Wave Doppler), Color Doppler, Amplitude Doppler (Color Flow Angiography), TDI (Tissue Doppler Imaging), 3D Imaging, 4D Imaging, Real Time Tissue Elastography, and Real Time Virtual Sonography.

## 6. Comparison to predicate device:

The Hitachi Aloka Medical, Ltd. Arietta70 / AriettaS70 / AriettaV70 Diagnostic Ultrasound device is technically comparable and substantially equivalent to the HI VISION Ascendus Diagnostic Ultrasound Scanner [K110673] and Hitachi Prosound F75 Diagnostic Ultrasound Scanner [K123828]. The subject and predicate systems are track 3 systems that incorporate the same fundamental and scientific technologies. Both the subject and predicate device systems have the same intended use/indications for use.

Function	Subject	Predicates	
	Hitachi Aloka Medical, Ltd. Arietta 70*/ Arietta S70*/ Arietta V70*	Hi Vision Ascendus K110673	Prosound F75 K123828
Color Flow	x	x	x
TDI (Tissue Doppler Imaging)	x	x	x
Trapezoid	x	x	x
Measurement function	x	x	x
Dual Doppler	x	x	x
Marking assist display	x	x	NA
Real-time Doppler Auto Trace	x	x	x
Spatial Compound	x	x	x
FAM (Free Angular M-mode)	x	x	x
HI REZ/ AIP	x	x	x
EyeBallEF	x	x	NA
DSD (Dynamic Slow motion Display)	x	NA	x
CHI/ CHE	x	x	x
EFV (Extended Field of View)	x	x	x
Stress Echo	x	x	x
DICOM	x	x	x
DICOM SR	x	x	x
DICOM QR	x	x	x
Real-time Tissue Elastography	x	x	x
RVS (Real-time Virtual Sonography)	x	x	NA
Picture in Picture	x	x	NA
Freehand 3D	x	x	x
Real-time 3D	x	x	x
3D STIC	x	x	x
Automated IMT measurement	x	x	x
Automated NT measurement	x	NA	x
ET (eTracking/ echo Tracking)	x	NA	x
FMD (Flow Mediated Dilatation)	x	NA	x
WI (Wave Intensity)	x	NA	x

\*The Hitachi Arietta 70 / Arietta S70 / Arietta V70 are exactly the same with the exception of different color outer shell.

21 CFR Part 807.92, Section b

1. Non-clinical Testing

No new hazards were identified with the subject device. The subject device and its transducers have been evaluated for acoustic output, biocompatibility, cleaning & disinfection effectiveness, electromagnetic compatibility, as well as electrical and mechanical safety, and have been found to conform to applicable medical device safety standards.

2. Clinical testing:

None required

3. Conclusions:

The Hitachi Aloka Medical, Ltd. Arietta70/ AriettaS70/ AriettaV70 Diagnostic Ultrasound scanner is substantially equivalent in safety and effectiveness to the predicate device;

- The subject and predicate device(s) are both indicated for diagnostic ultrasound imaging and fluid flow analysis.
- The subject and predicate device(s) have the same gray scale and Doppler capabilities.
- The subject and predicate device(s) have the same essential technology for imaging, Doppler functions, and signal processing.
- The subject and predicate device(s) have acoustic level below the Track 3 FDA limits.
- The subject and predicate device(s) are manufactured in accordance to FDA 21 CFR 820 Quality System Regulations.
- The subject and predicate device(s) are designed and manufactured to the same electrical and physical safety standards.
- The subject and predicate device(s) are manufactured with materials that have been tested in accordance to ISO 10993-1; all biocompatibility testing has been conducted in accordance to each component material characterization, type of body contact, and duration contact risk profile.
- The subject and predicate device(s) are designed to be re-usable and provide instructions for cleaning, disinfection, and sterilization in the Ultrasound system and transducer manuals.

**END OF SUMMARY**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

March 28, 2014

Hitachi Aloka Medical, Ltd. (Hitachi Aloka Medical America)  
% Ms. Angela Van Arsdale  
RA/QA Manager  
10 Fairfield Blvd.  
WALLINGFORD CT 06492-7502

Re: K134016

Trade/Device Name: Arietta70 / AriettaS70 / AriettaV70 Diagnostic Ultrasound Scanner  
Regulation Number: 21 CFR 892.1550  
Regulation Name: Ultrasonic pulsed doppler imaging system  
Regulatory Class: II  
Product Code: IYN, IYO, ITX  
Dated: January 24, 2014  
Received: January 29, 2014

Dear Ms. Van Arsdale:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the Arietta 70/Arietta S70/Arietta V70 Diagnostic Ultrasound Scanner, as described in your premarket notification:

<u>Transducer Model Number</u>		
C251	C41V1	C41V
CC41R	R41R	C42T
L64	S12	VC34
VC41V	C41L47RP	UST-2265-2
UST-5293-5	UST-52126	C41
C42	C35	C22P
C25P	C41RP	C42K
L34	L441	L55
L46K	S31	S31KP
VL54	UST-2266-5	UST-5418

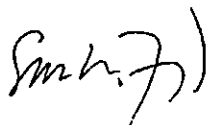
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for

Janine M. Morris  
Director, Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

**Indications for Use**

510(k) Number (if known)  
K134016

Device Name  
Hitachi Arietta70/AriettaS70/AriettaV70 Ultrasound Diagnostic System

**Indications for Use (Describe)**

The Hitachi Aloka Medical, Ltd. Arietta70/ AriettaS70 /AriettaV70 is intended for use by trained personnel (doctor, sonographer, etc.) for the diagnostic ultrasound evaluation of Abdominal, Cardiac, Intra-operative, Fetal, Pediatric, Small Organ, Peripheral vessel, Biopsy, Trans-rectal, Trans-vaginal, Musculoskeletal, Neonatal Cephalic, Adult Cephalic, Endoscopy, Intra-luminal, Gynecology, Urology and Laparoscopic clinical applications.

The Modes of Operation are B mode, M mode, PW mode (Pulsed Wave Doppler), CW mode (Continuous Wave Doppler), Color Doppler, Amplitude Doppler (Color Flow Angiography), TDI (Tissue Doppler Imaging), 3D Imaging, 4D Imaging, Real Time Tissue Elastography, and Real Time Virtual Sonography.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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FOR FEDERAL USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov)

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & II)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P	P	P	P	P
	Abdominal	Pa	Pa	Pa	Pa	Pa	Pa	Pa
	Intra-operative (Spec.)	Ph	Pb	Pb		Ph	Ph	Pb
	Intra-operative (Neuro.)	P	P	P	P	P	P	P
	Laparoscopic	P	P	P		P	P	P
	Pediatric	P	P	P	P	P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd	Pd	Pd	Pd	Pd
	Neonatal Cephalic	P	P	P	P	P	P	P
	Adult Cephalic	P	P	P	P	P	P	P
	Trans-rectal	Ph	Ph	Ph		Ph	Ph	Ph
	Trans-vaginal	Pf	Pf	Pf		Pf	Pf	Pf
	Trans-urethral							
	Trans-esoph. (non-Card.)	P	P	P		P	P	P
	Musculo-skel. (Convent.)	P	P	P		P	P	P
	Musculo-skel. (Superfic.)	P	P	P		P	P	P
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	P	P	P	P	P	P	P
	Cardiac Pediatric	P	P	P	P	P	P	P
	Trans-esophageal (cnrd.)	P	P	P	P	P	P	P
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P	P	P	P	P
	Other (spec.)	P	P	P		P	P	P

N = new indication. P = previously cleared in K123828 and K130308

\*Combination of each operating mode. B, M, PWD, CWD and Color Doppler.

\*\*Amplitude Doppler (Color Flow Angiography), Tissue Doppler Imaging, 3D Imaging, 4D Imaging, Real Time Tissue Elastography, Real Time Virtual Sonography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery  
(excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy

Subscript "e": Includes imaging for guidance of trans-rectal biopsy

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

*Prescription Use Only (Per 21 CFR 801.109)*

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Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

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Division of Radiological Health

Office of *In Vitro* Diagnostics and Radiological Health

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: C251

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P
	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel (Convent.)							
	Musculo-skel (Superf.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication P = previously cleared in K110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler

\*\*Amplitude Doppler (Color Flow Angiography), Tissue Doppler Imaging, 3D Imaging, Real Time Virtual Sonography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis)

Subscript "b": Includes imaging of organs and structures exposed during surgery  
(excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy

*Prescription Use Only (Per 21 CFR 801.109)*

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: C41V1

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	Pe	Pe	Pe		Pe	Pe	Pe
	Trans-vaginal	Pf	Pf	Pf		Pf	Pf	Pf
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.) Gynecological	P	P	P		P	P	P

N = new indication P = previously cleared in K130308

\*Combination of each operating mode, B, M, PWD, and Color Doppler

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Tissue Elastography, Real Time Virtual Sonography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery  
(excluding neurosurgery and laparoscopic procedures)

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: C41V

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	Pe	Pe	Pe		Pe	Pe	Pe
	Trans-vaginal	Pf	Pf	Pf		Pf	Pf	Pf
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.) Gynecological	P	P	P		P	P	P

N = new indication. P = previously cleared in K130308

\*Combination of each operating mode, B, M, PWD, and Color Doppler.

\*\*Amplitude Doppler (Color Flow Angiography). 3D Imaging. Real Time Tissue Elastography. Real Time Virtual Sonography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery  
(excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy.

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: CC41R

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	Pe	Pe	Pe		Pe	Pe	Pe
	Trans-vaginal	Pf	Pf	Pf		Pf	Pf	Pf
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler.

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Tissue Elastography, Real Time Virtual Sonography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis)

Subscript "b": Includes imaging of organs and structures exposed during surgery  
(excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy.

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

*Prescription Use Only (Per 21 CFR 801.109)*

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: R41R

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	P	P
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K130308

\*Combination of each operating mode, B, M, PWD, and Color Doppler.

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Tissue Elastography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery  
(excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy.

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

*Prescription Use Only (Per 21 CFR 801.109)*

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: C42T

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)	P	P	P		P	P	P
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Tissue Elastography, Real Time Virtual Sonography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery  
(excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

*Prescription Use Only (Per 21 CFR 801.109)*

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: L64

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P		P	P	P
	Musculo-skel. (Superfic.)	P	P	P		P	P	P
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P
	Other (spec.)							

N = new indication, P = previously cleared in K130308

\*Combination of each operating mode, B, M, PWD, and Color Doppler.

\*\*Amplitude Doppler (Color Flow Angiography). Real Time Tissue Elastography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy

Subscript "e": Includes imaging for guidance of trans-rectal biopsy

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: S12

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P	P	P	P	P
	Abdominal	P	P	P	P	P	P	P
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	P
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic	P	P	P	P	P	P	P
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	P	P	P	P	P	P	P
	Cardiac Pediatric	P	P	P	P	P	P	P
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P	P	P	P	P
	Other (spec.)							

N = new indication. P = previously cleared in K110673

\*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

\*\*Amplitude Doppler (Color Flow Angiography), Tissue Doppler Imaging, 3D Imaging, 4D Imaging, Real Time Tissue Elastography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy.

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: VC34

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P
	Abdominal	P	P	P		P	P	P
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	P	P	P		P	P	P
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.) Gynecological	P	P	P				

N = new indication. P = previously cleared in K1110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler.

\*\*Amplitude Doppler (Color Flow Angiography), Tissue Doppler Imaging, 3D Imaging, 4D Imaging

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery  
(excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy.

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: VC41V

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	P	P	P		P	P	P
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.) Gynecological	P	P	P		P	P	P

N = new indication. P = previously cleared in K123828

\*Combination of each operating mode, B, M, PWD, and Color Doppler.

\*\*Amplitude Doppler (Color Flow Angiography), 4D Imaging.

Additional Comments:

Subscript "a" Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b" Includes imaging of organs and structures exposed during surgery  
(excluding neurosurgery and laparoscopic procedures).

Subscript "c" Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d" Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e" Includes imaging for guidance of trans-rectal biopsy.

Subscript "f" Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g" For pediatric patients

Subscript "h" Includes imaging for guidance of trans-rectal biopsy.

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: C41L47RP

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	Ph	Ph	Ph		Ph	Ph	Ph
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K110673

\*Combination of each operating mode. B, M, PWD, and Color Doppler.

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Tissue Elastography, Real Time Virtual Sonography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery  
(excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: UST-2265-2

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph (non-Card.)							
	Musculo-skel (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult				P			
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication P = previously cleared in K123828

\*Combination of each operating mode: B, M, PWD, CWD and Color Doppler

\*\*Amplitude Doppler (Color Flow Angiography), Tissue Doppler Imaging, 3D Imaging, 4D Imaging, Real Time Tissue Elastography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery  
(excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: UST-5293-5

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	P	P	P	P	P	P	P
	Cardiac Pediatric							
	Trans-esophageal (card.)	P	P	P	P	P	P	P
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication, P = previously cleared in K123828

\*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

\*\*Amplitude Doppler (Color Flow Angiography), Tissue Doppler Imaging

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis)

Subscript "b": Includes imaging of organs and structures exposed during surgery

(excluding neurosurgery and laparoscopic procedures)

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: UST-52126

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph (non-Card.)							
	Musculo-skel (Convent.)							
	Musculo-skel (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	P	P	P	P	P	P	P
	Cardiac Pediatric							
	Trans-esophageal (card.)	P	P	P	P	P	P	P
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K123828

\*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

\*\*Amplitude Doppler (Color Flow Angiography), Tissue Doppler Imaging

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy.

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: C41

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P		P	P	P
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P
	Other (spec.)							

N = new indication P = previously cleared in K130308

\*Combination of each operating mode, B, M, PWD and Color Doppler

\*\*Amplitude Doppler (Color Flow Angiography), Real Time Tissue Elastography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery

(excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: C42

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa
	Intra-operative (Spec.)	Pb	Pb	Pb		Pb	Pb	Pb
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd
	Neonatal Cephalic	P	P	P		P	P	P
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P
	Other (spec.)							

N = new indication. P = previously cleared in K130308

\*Combination of each operating mode: B, M, PWD and Color Doppler

\*\*Amplitude Doppler (Color Flow Angiography), 3D imaging, Real Time Tissue Elastography, Real Time Virtual Sonography

Additional Comments:

Subscript "a" Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b" Includes imaging of organs and structures exposed during surgery  
(excluding neurosurgery and laparoscopic procedures)

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy.

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: C35

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P	P	P	P	P
	Abdominal	P	P	P	P	P	P	P
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	P
	Small Organ (Spec.)	Pc	Pc	Pc	Pc	Pc	Pc	Pc
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K110673

\*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

\*\*Amplitude Doppler (Color Flow Angiography), Tissue Doppler Imaging, 3D Imaging, 4D Imaging, Real Time Tissue Elastography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery  
(excluding neurosurgery and laparoscopic procedures)

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy.

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: C22P

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P
	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler.

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Virtual Sonography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery  
(excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy.

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: C25P

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P
	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K110673

\*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Virtual Sonography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy.

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

*Prescription Use Only (Per 21 CFR 801.109)*

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: C41RP

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	Pe	Pe	Pe		Pe	Pe	Pe
	Trans-urethral	Pf	Pf	Pf		Pf	Pf	Pf
	Trans-esoph (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K123828

\*Combination of each operating mode. B, M, PWD, CWD and Color Doppler.

\*\*Amplitude Doppler (Color Flow Angiography), Tissue Doppler Imaging, 3D Imaging, 4D Imaging, Real Time Tissue Elastography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery

(excluding neurosurgery and laparoscopic procedures)

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy

Subscript "e": Includes imaging for guidance of trans-rectal biopsy

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: C42K

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)	Pb	Pb	Pb		Pb	Pb	Pb
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd
	Neonatal Cephalic	P	P	P		P	P	P
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K130308

\*Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler (Color Flow Angiography)

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery  
(excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy.

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: L34

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	Pa	Pa	Pa	Pa	Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd	Pd	Pd	Pd	Pd
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P	P	P	P	P
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P	P	P	P	P
	Other (spec.)							

N = new indication. P = previously cleared in K130308

\*Combination of each operating mode. B, M, PWD, CWD and Color Doppler.

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Tissue Elastography, Real Time Virtual Sonography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis)

Subscript "b": Includes imaging of organs and structures exposed during surgery  
(excluding neurosurgery and laparoscopic procedures)

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: L441

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)	Pd	Pd	Pd	Pd	Pd	Pd	Pd
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	Pd	Pd	Pd	Pd	Pd	Pd	Pd
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	Pd	Pd	Pd	Pd	Pd	Pd	Pd
	Other (spec.)							

N = new indication. P = previously cleared in K123828

\*Combination of each operating mode: B, M, PWD, CWD and Color Doppler

\*\*Amplitude Doppler (Color Flow Angiography), Tissue Doppler Imaging, 3D Imaging, Real Time Tissue Elastography, Real Time Virtual Sonography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery  
(excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: 1.55

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	Pa	Pa	Pa	Pa	Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd	Pd	Pd	Pd	Pd
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P	P	P	P	P
	Musculo-skel. (Superfic.)	P	P	P	P	P	P	P
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P	P	P	P	P
	Other (spec.)							

N = new indication, P = previously cleared in K130308

\*Combination of each operating mode, B, M, PWD, CWD, and Color Doppler.

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Tissue Elastography, Real Time Virtual Sonography.

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy.

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: L46K

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)	Pb	Pb	Pb		Pb	Pb	Pb
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K123828

\*Combination of each operating mode, B, M, PWD, CWD and Color Doppler

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Virtual Sonography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis)

Subscript "b": Includes imaging of organs and structures exposed during surgery

(excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: S31

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P	P	P	P	P	P	P
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	P
	Small Organ (Spec.)							
	Neonatal Cephalic	P	P	P	P	P	P	P
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph (non-Card)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	P	P	P	P	P	P	P
	Cardiac Pediatric	P	P	P	P	P	P	P
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K130308

\*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

\*\*Amplitude Doppler (Color Flow Angiography). Tissue Doppler Imaging

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis)

Subscript "b": Includes imaging of organs and structures exposed during surgery  
(excluding neurosurgery and laparoscopic procedures)

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy

Subscript "e": Includes imaging for guidance of trans-rectal biopsy

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: S31KP

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)	Pb	Pb	Pb	Pb	Pb	Pb	Pb
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K123828

\*Combination of each operating mode, B, M, PWD, CWD and Color Doppler

\*\*Amplitude Doppler (Color Flow Angiography)

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy.

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: VL54

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P	P	P		P	P	P
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	Pc	Pc	Pc		Pc	Pc	Pc
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P		P	P	P
	Musculo-skel. (Superfic.)	P	P	P		P	P	P
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P
	Other (spec.)							

N = new indication. P = previously cleared in K110673

\*Combination of each operating mode, B, M, PWD, and Color Doppler.

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, 4D Imaging, Real Time Tissue Elastography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis)

Subscript "b": Includes imaging of organs and structures exposed during surgery  
(excluding neurosurgery and laparoscopic procedures)

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

*Prescription Use Only (Per 21 CFR 801.109)*

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: US1-2266-5

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic  Fetal Imaging & Other	Ophthalmic							
	Fetal							
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Cardiac	Intra-luminal							
	Other (spec.)							
	Cardiac Adult				P			
	Cardiac Pediatric							
Peripheral Vessel	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel				P			
	Other (spec.)							

N = new indication. P = previously cleared in K123828

\*Combination of each operating mode. B, M, PWD, CWD and Color Doppler.

\*\*Amplitude Doppler (Color Flow Angiography). Tissue Doppler Imaging. 3D Imaging. 4D Imaging. Real Time Tissue Elastography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis)

Subscript "b": Includes imaging of organs and structures exposed during surgery

(excluding neurosurgery and laparoscopic procedures)

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: UST-5418

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)	N	N	N		N	N	N
	Intra-operative (Neuro.)							
	Laparoscopic	P	P	P		P	P	P
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K130308

\*Combination of each operating mode, B, M, PWD, and Color Doppler.

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Tissue Elastography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery  
(excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy.

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

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